

# Notice of Allowability

Application No.

10/762,880

Examiner

Michael C Astorino

Applicant(s)

WILLIAMS ET AL.

Art Unit

3736

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Terminal Disclaimer filed 9/1/2004.
2. ☒ The allowed claim(s) is/are 1-19.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached.
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

The following is an examiner's statement of reasons for allowance: Eslyed et al., Schauss et al. and Boyer et al. (each cited by applicant) disclose various aspects of the applicants claimed invention including defining a plurality of risk groups based on predefined risk parameters, defining a set of information to be obtained by a patient which is probative of the risk on a adverse side effect, and registering patients, physicians and pharmacies in a computer medium for the distribution of a drug which is contraindicated, however each reference fails to disclose a prescription approval code from a risk group assignment. Furthermore, none of the prior art by itself or in combination has shown a prescription approval code from a risk group assignment or "upon a determination that the risk is acceptable, generating the prescription approval before the prescription is filled." Moreover, the prior art does not disclose such a method for "treating erythema nodosum leprosum using thalidomide while restricting access to thalidomide for patients for whom thalidomide may be contraindicated ...", "treating a patient having a disease or condition which is responsive to thalidomide while restricting access to thalidomide for patients for whom thalidomide may be contraindicated, the method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has become aware of approval of a prescription for thalidomide for the patient from a computer readable storage medium, the generation of the prescription approval...", or "treating a disease with a drug known or suspected of having teratogenic properties while restricting access to the drug by patients for whom the drug may be contraindicated the method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has become aware of approval of a prescription for thalidomide for the patient from a computer readable storage medium, the generation of the prescription approval."

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C Astorino whose telephone number is 703-306-9067. The examiner can normally be reached on Monday-Friday, 10:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Astorino  
September 22, 2004

  
MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700